



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0086]

Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council; Establishment of a Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on policy issues that may be considered by the FDA Combination Product Policy Council (Council). These comments will help the Agency identify and address combination product policy issues that need clarification through guidance, notice and comment procedures, or other means.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-0086 for "Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nina L. Hunter, Office of Medical Products and Tobacco (OMPT), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 2312, Silver Spring, MD 20993-0002, 301-796-6171, FAX: 301-847-8514, [CombinationProductCouncil@fda.hhs.gov](mailto:CombinationProductCouncil@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In April 2016, FDA established the Council to ensure better coordination of combination product policy development and implementation across the Agency and consistent, predictable communication of combination product policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by the Deputy Commissioner of OMPT, the Council provides a senior-level forum through which combination product policy issues can be raised, considered, developed, and implemented. Council members include the following senior leaders: The Center Directors and one representative from the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health; the Office Director from the Office of Combination Products (OCP); and the Associate Commissioner for Special Medical Programs. Additional staff from the Centers and other FDA offices provide expertise as needed for specific combination product policy topics under consideration. While there are various other mechanisms available to raise issues for Agency consideration, by establishing this docket, FDA seeks to provide a forum for the public to recommend specific topics that should have direct, collective engagement and consideration by the Council. The Agency believes that

this process will also further enhance transparency in FDA's approach to policy development and implementation.

## II. Range of Policy Issues To Be Considered

FDA envisions a variety of combination product policy topics that may be appropriate for consideration by the Council, which typically would meet one or more of the following criteria:

- A novel combination product policy issue requiring senior management input;
- An identical issue on which FDA seems to have taken inconsistent combination product policy positions;
- An existing combination product policy position that should be reconsidered in light of scientific or regulatory advances; or
- A combination product policy that may be triggered by a specific combination product, but that will be applicable to other combination products.

## III. Establishment of a Docket and Request for Comments

The docket is being made available for public suggestions, recommendations, and comments relating to the combination product policy criteria identified in this document that may warrant consideration by the Council. Submissions should describe the following: (1) The combination product policy issue recommended for discussion (e.g., clarifying previous advice or precedents on a specified combination product policy topic, reconciling apparently differing perspectives within FDA or between FDA and regulated industry on a specified combination product policy topic), (2) the rationale for doing so, including why it requires direct engagement by the Council, (3) recommendations on how the combination product policy issue could be addressed; and (4) existing policy documents (e.g., final guidance) relevant to the combination product policy issue.

Note that combination product policy issues concerning any draft guidance or proposed rule should be submitted to the docket for that draft guidance or rulemaking; product-specific disputes should first be addressed through the appropriate appeals mechanism of the Center or other Agency component involved; and general recommendations for topics to address through guidance or rulemaking should be made to the Center, OCP, or other relevant Agency component through the mechanisms provided by that component.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment. In general, combination product policy decisions reached by the Council are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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